

THE SUPPORTING STATEMENT

A. Justification

1. Circumstances of Information Collection

The Health Resources and Services Administration (HRSA), Healthcare Systems Bureau (HSB) is requesting approval from the Office of Management and Budget (OMB) for the enrollment forms and re-certification of this information from entities in the 340B Drug Pricing Program. Section 602 of Public Law 102-585, the Veterans Health Care Act of 1992, enacted section 340B (“Limitation on Prices of Drugs Purchased by Covered Entities”)of the Public Health Service Act (PHS Act). Covered entities who choose to participate in the section 340B Drug Pricing Program must meet the eligibility requirements in 340B(a)(4) and must comply with the requirements of 340B(a)(5)of the PHS Act.

In response to the statutory mandate of 340B (a)(9) to notify drug manufacturers of the identities of covered entities and the mandate of section 340B(a)(5)(A)(ii) to establish a mechanism to ensure against duplicate discounts and the ongoing responsibility to administer the 340B Drug Pricing Program, HRSA Office of Pharmacy Affairs (OPA) developed a process of registering covered entities and of addressing those mandates.

As part of the re-registration process implemented pursuant to “covered entity compliance” provisions added to 340B(d)(2) in 2010, OPA included a certification of compliance in the recertification process. After initiating the recertification process it was subsequently determined that these compliance elements needed be cleared by OMB. A general review of the forms was done with revisions to those forms including the compliance certification requirements which have been now included in this package.

2. Purpose and Use of Information

To register and certify the newly eligible safety net health care providers, OPA requires entities to submit an application consisting of administrative information (e.g. name and address of organization, shipping and billing arrangements, Medicaid participation), certifying information and signatures from appropriate entity level authorizing officials and state/local government representatives. The purpose of this registration information is to determine eligibility for the 340B Program. This information is received once, at the time of application, verified according to 340B Program requirements and entered into the 340B database. Accurate records are critical to implementation of the 340B legislation especially to prevent the legal prohibitions of drug diversion and duplicate discounts. To maintain accurate records, OPA requests entities to submit modifications to any administrative information that they submitted when initially enrolling into the program. 340B covered entities have an ongoing responsibility to immediately notify OPA in the event of any change in eligibility for the 340B Drug Pricing Program. No less than on an annual basis, entities will need to certify the accuracy of the information provided and continued maintenance of their eligibility and to comply with statutory mandates of the program. OPA is also required by statute to develop a system to verify all of the covered information contained in the database.

3. Use of Improved Information Technology

The burden requirement for registering and for recertifying covered entities in the 340B Program is minimal. To improve public transparency and agency efficiency, administrative information collected regarding the covered entity is available in a public database.

The recertification process for 340B entities and some application processes are electronic. For those applications that are not currently on-line, respondents are encouraged to transmit their materials via the least burdensome process, whether it is by email or fax or by submitting paper applications.

4. Efforts to Identify Duplication

The information collected is only for the purposes of the 340B Drug Pricing Program and is not available elsewhere. The information requested is not available from any other source.

5. Involvement of Small Entities

The data collection does not have a significant impact on small businesses or other small entities.

6. Consequences If Information Collected Less Frequently

Each entity must respond only once when applying to register for the program and following enrollment, once a year to recertify program eligibility. If this information is not collected, eligibility may not be verified and statutory mandates of section 340B of the PHS Act may not be addressed. It is essential that eligibility information remain accurate to insure that manufacturers are not required to extend discounts to covered entities no longer eligible for the 340B Drug Pricing Program. It is also required that HRSA ensure that drugs purchased under 340B are not subject to State Medicaid rebate claims. Section 340B(D)(2)(b) requires that covered entities regularly update information (at least annually) and that HRSA verify that information.

7. Consistency With the Guidelines in 5 CFR 1320.5(d)(2)

This information collection is consistent with 5 CFR 1320.5(d)(2).

8. Consultation Outside the Agency

Section 8A:

The notice required by 5 CFR 1320.8(d) was published in the *Federal Register* on March 19, 2012 (Vol. 77, No. 53, pages 16042-16043).

Four comments were received:

1. A comment from a participating pharmaceutical manufacturer emphasized the importance of having real time eligibility information on the database. This manufacturer also recommended changes in the registration of outpatient facilities involving specification of the address utilized, additional information regarding parent organization non-profit status, more restrictive requirements regarding for profit status, the timeframe of notification of any change of information, and the inclusion of Pharmacy Identifiers.
2. A comment from a pharmaceutical industry organization described utilized recertification language as essential to ensure covered entity understanding of 340B requirements and proposed additional language involving the parent organization, inventory systems and private hospital eligibility. This letter included comments on the registration of child sites and the use of ship to addresses, the registration of pharmacies, outpatient facilities that provide referral services, recertification of private hospitals, covered entity ownership status, recertification timeframes, and availability of enrollment and recertification information on the website.
3. A comment from a covered entity hospital stated that the recertification process took far more time to complete and was not yet completed. This comment stated there were a number of unanswered questions and conflicting information from manufacturers. The comment indicated that it was difficult to predict the necessary information to provide to state Medicaid agencies.
4. A comment from a hospital organization stated support of recertification and that it is critical that 340B enrollment information be accurate on the 340B website. This organization expressed concern that the recertification language may be invalid due to not having been approved by OMB, and inadequate notice. The comment expressed concern about the amount of time provided to complete the process. The comment expressed the view that some of the eight statements included may not be necessary for the proper performance of HRSA. The comment expressed the view that the requirement under number 2 may be practically impossible to properly evaluate. The commenter stated that the time estimate significantly underestimated the time to complete. The commenter recommended changing element #2 to reflect the status at the time of recertification. The commenter recommended more advanced notice of the language in order to reduce burden. The commenter expressed concerns about compliance with the federal Administrative Procedure Act. The commenter asserted that statements #2, #7 and #8 are inconsistent with published guidelines.

In response to the comments from the manufacturer and manufacturer organization, HRSA continues to revise the registration process and improve instructions on the use of forms and is evaluating the appropriateness of requiring additional information. HRSA has opted not to include additional information or placing additional restrictions in the forms at this time. HRSA will continue to evaluate the need for improved instructions and provide improved Frequently Asked questions.

In response to comments from the hospital and hospital organization, HRSA has determined that the recertification information must be submitted to OMB . HRSA also revised some of the

statements in response to similar comments and experience with the form. Element #2 was revised to include only the past year. HRSA disagrees that the elements as revised are in conflict with published guidelines and has concluded that all covered entities have been required to have systems in place to ensure against diversion and duplicate discounts and maintain auditable records since the inception of the program. That this was expressly written in greater detail in the contract pharmacy guidelines does not alter the necessity that covered entities maintain such systems. HRSA also finds with respect to element 7 that covered entities have had the obligation to self-report material breaches since the inception of the 340B program. This is not in conflict with guidelines on dispute resolution as simply notifying the Office of Pharmacy Affairs about the existence of a violation does not displace or conflict with the existing resolution process. Statement 8 has been revised in response to comment.

The first year of certification did result in some confusion among hospitals and HRSA has accepted all requests for extensions and worked with covered entities. HRSA recognizes that the time will vary from covered entity to covered entity and has sought additional testing. It is also noted that the definition of covered entity in section 340B(a)(4) includes compliance with the requirements of section 340B(a)(5) and requiring certification of compliance with the statutory requirements is consistent with the need to verify eligibility of all covered entities on the database. Covered entities have been required to be in compliance with these requirements since the inception of the program.

Section 8B:

Consultation and review of the materials were conducted outside of the agency. The burden estimate and the clarity of the forms were reviewed and found to be appropriate by the following organizations and grantees:

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9. Remuneration of Respondents

Respondents will not receive any remuneration.

10. Assurance of Confidentiality

Application and eligibility information regarding entities that is collected for this submission does not contain any personal identifiers and therefore, does not apply to the Privacy Act.

11. Questions of a Sensitive Nature

This data collection does not request sensitive information from the respondent.

12. Estimates of Annualized Hour Burden

| Reporting Requirement | Number of Respondents | Responses per Respondent | Total Responses | Hours per Response | Total Burden Hours | Wage Rate (Per hour) | Total Cost |
|--|-----------------------|--------------------------|-----------------|--------------------|--------------------|----------------------|------------|
| HOSPITAL ENROLLMENT, ADDITIONS & RECERTIFICATIONS | | | | | | | |

| | | | | | | | |
|--|-------|---|-------|-----|---------|------|----------|
| 340B Program Registrations & Certifications for Hospitals | 546 | 1 | 546 | 2.0 | 1,092 | \$40 | \$43,680 |
| Certifications to Enroll Hospital Outpatient Facilities | 606 | 1 | 606 | .50 | 303 | \$40 | \$12,120 |
| Hospital Annual Recertification | 4,842 | 1 | 4,842 | .50 | 2,421 | \$40 | \$96,840 |
| REGISTRATIONS AND RECERTIFICATIONS FOR ENTITIES OTHER THAN HOSPITALS | | | | | | | |
| 340B Registrations for Community Health Centers | 253 | 1 | 253 | 1.0 | 253 | \$30 | \$7,590 |
| 340B Registrations for Family Planning Programs, STD/TB Clinics and Various Other Eligible Entity Types | 353 | 1 | 353 | 1.0 | 353 | \$30 | \$10,590 |
| Community Health Center Annual Recertification | 4,507 | 1 | 4,507 | .50 | 2,253.5 | \$30 | \$67,605 |
| Family Planning Annual Recertification | 3,879 | 1 | 3,879 | .50 | 1,939.5 | \$30 | \$58,185 |
| STD & TB Annual Recertification | 2,754 | 1 | 2,754 | .50 | 1,377 | \$30 | \$41,310 |
| Annual Recertification for entities other than Hospitals, Community Health Centers, Family Planning, STD or TB Clinics | 1,174 | 1 | 1,174 | .50 | 587 | \$30 | \$17,610 |
| OTHER INFORMATION COLLECTIONS | | | | | | | |
| Submission of Administrative Changes for any Covered Entity | 2,500 | 1 | 2,500 | .50 | 1,250 | \$30 | \$37,500 |
| Submission of Administrative Changes for any Manufacturer | 350 | 1 | 350 | .50 | 175 | \$15 | \$2,625 |

| CONTRACTED PHARMACY SERVICES REGISTRATION & RECERTIFICATIONS | | | | | | | | |
|--|--------|---|--------|-----|--------|------|-----------|--|
| Contracted Pharmacy Services | 2,500 | 1 | 2,500 | 1.0 | 2,500 | \$50 | \$125,000 | |
| Registration | | | | | | | | |
| Pharmaceutical Pricing Agreement | 200 | 1 | 200 | 1.0 | 200 | \$50 | \$10,000 | |
| TOTAL | 24,464 | | 24,464 | | 14,704 | | \$530,655 | |

340B Program Registrations & Certifications for Hospitals: include the (1) 340B Program Registration Form, (2) Certification of Contract Between Private, Non-Profit DSH and State/Local Government, and (3) Certification Regarding Non-Participation of a DSH, Children’s Hospital in a Group Purchasing Organization except Critical Access, Sole Community and Rural Referral Center Hospital. It is estimated that approximately 546 respondents take 2 hours to complete these forms to register in the program, resulting in a total annual burden of 1092 hours ($546 \times 2 = 1092$ hrs.) for Hospitals.

Certifications to Enroll Hospital Outpatient Facilities: include the (1) 340B Registration Form for Outpatient Facilities Using Medicare Cost Report. It is estimated that 606 hospitals take 0.50 hours each to enroll their outpatient facilities, resulting in a total annual burden of 303 hours ($606 \times 0.50 = 303$ hrs.).

Hospital Annual Recertification: refers to an electronic process where covered entities ensure they continue to be eligible and in compliance with statutory mandates of the program by confirming their administration information that is stored in the 340B public database. It is estimated that 4842 hospitals take 0.5 hrs to recertify, resulting in a total annual burden of 2421 hours ($4842 \times 0.5 = 2421$ hrs.).

340B Registrations for Community Health Centers: refers to the form entitled 340B Registration Form for Covered Entities. It is estimated that 253 entities take 1 hr to complete this form to register in the program, resulting in a total annual burden of 253 hours for these entities ($253 \times 1 = 253$ hrs.).

340B Registrations for Family Planning Programs, STD/TB Clinics and Various Other Eligible Entity Types: refers to the form entitled 340B Registration Form for Covered Entities. It is estimated that 353 entities take 1 hr to complete this form to register in the program, resulting in a total annual burden of 353 hours for these entities ($353 \times 1 = 353$ hrs.).

Community Health Center Annual Recertification: refers to an electronic process where covered entities ensure they continue to be eligible and in compliance with statutory mandates of the program by confirming their administration information that is stored in the 340B public database. It is estimated that 4507 Community Health Centers take 0.5 hrs to recertify, resulting in a total annual burden of 2253.5 hours ($4507 \times 0.5 = 2253.5$ hrs.).

Family Planning Annual Recertification: refers to an electronic process where covered entities ensure they continue to be eligible and in compliance with statutory mandates of the program by confirming their administration information that is stored in the 340B public database. It is estimated that 3879 Family Planning take 0.5 hrs to recertify, resulting in a total annual burden of 1939.5 hours ($3879 \times 0.5 = 1939.5$ hrs.).

STD & TB Annual Recertification: refers to an electronic process where covered entities ensure they continue to be eligible and in compliance with statutory mandates of the program by confirming their administration information that is stored in the 340B public database. It is estimated that 2754 STD & TB take 0.5 hrs to recertify, resulting in a total annual burden of 1377.5 hours ($2754 \times 0.5 = 1377.5$ hrs.).

Annual Recertification for entities other than Hospitals, Community Health Centers, Family Planning, STD or TB Clinics: refers to an electronic process where covered entities ensure they continue to be eligible and in compliance with statutory mandates of the program by confirming their administration information that is stored in the 340B public database. It is estimated that 1174 other than Hospitals, Community Health Centers, Family Planning, STD or TB Clinics take 0.5 hrs to recertify, resulting in a total annual burden of 587 hours ($1174 \times 0.5 = 587$ hrs.).

Submission of Administrative Changes for any Covered Entity: refers to the form entitled 340B covered entities to request any change to be made in 340B public database by OPA staff. It is estimated that 2500 entities take 0.50 hours each to complete this form to request change in the 340B public database, resulting in a total annual burden of 1250 hours ($2500 \times 0.50 = 1250$ hrs.).

Submission of Administrative Changes for any Manufacturer: refers to the form entitled 340B manufacturer to request any change to be made in 340B public database by OPA staff. It is estimated that 350 manufacturers take 0.50 hours each to complete this form to request change in the 340B public database, resulting in a total annual burden of 175 hours ($350 \times 0.50 = 175$ hrs.).

Contracted Pharmacy Services Registration: refers to the form entitled 340B Registration Form for Contract Pharmacy Services Registration. It is estimated that 2500 entities take 1 hour to complete this form to register in the program, resulting in a total annual burden of 2500 hours for these entities ($2500 \times 1 = 2500$ hrs.).

Pharmaceutical Pricing Agreement (PPA): Pursuant to the Public Health Service Act (PHS Act), manufacturers sign the PPA agreeing to charge 340B covered entities at or below a specified maximum price known as the 340B ceiling price, for covered outpatient drug purchases. It is estimated that 200 manufacturers takes 1 hour to read and complete the attached form, resulting in a total annual burden of 200 hours ($200 \times 1 = 200$ hours).

13. Estimates of Annualized Cost Burden to Respondents

There is no capital, start up, or maintenance costs for the respondents.

14. Estimates of Annualized Cost to the Government

An estimated twenty percent of 1 FTEs at the GS 13 level, twenty percent of 1FTEs at the GS 12 level, and ten percent of 1FTE at the GS 11 & sixty percent of 1 FTE at GS 9 level are needed to review and process applications, certifications, and inquiries received for this program at an estimated annual cost of \$101,004.

15 Changes in Burden

Currently, there are 2,811.6 total reporting and record keeping burden hours in the OMB inventory. HRSA is requesting 14,704 burden hours, an increase of 11,892.4 hours. The increase is associated with the implementation of provisions of section 340B of the Public Health Service Act that were amended by sections 7101 and 7102 of the Affordable Care Act. This includes an expansion of eligible entities for the program under section 340B(a)(4) to include the addition of Free Standing Cancer Hospitals, Critical Access Hospitals (CAH), Rural Referral Centers (RRC) and Sole Community Hospitals (SCH). The amended statute also includes new covered entity compliance provisions in section 340B(a)(2) requiring the Secretary to adopt integrity provisions to improve oversight of program compliance, enable covered entities to regularly update information on the 340B website, and to verify information on the website. The change consists of increasing the estimated number of respondents to reflect the covered entities that are newly eligible to participate and implementation of the covered entity compliance provisions applicable to all participating 340B covered entities. In addition to, newly eligible entities and program integrity, HRSA Office of Pharmacy Affair (OPA) also included eight point attestation to all enrollment and recertification forms and manufacturer Pharmaceutical Pricing Agreement (PPA) which are also associated with the increase of burden hours. HRSA Office of Pharmacy Affair (OPA) recently determined that those eight point attestation and manufacturer Pharmaceutical Pricing Agreement (PPA) should be submitted to the OMB for review. Both eight point attestation and PPA are being added to current instruments to be approved by OMB.

16. Time Schedule, Publication and Analysis Plans

A three year clearance is being requested for this recurring data collection. There are no plans for tabulation, statistical analysis or publication of the information collected.

17. Exemption for Display of Expiration Date

No exemption is being requested.

18. Certifications

This information fully complies with the guidelines in 5 CFR 1320.9.